Remarks

In the Amendment filed on June 19, 2002, and in response to the restriction requirement under 35 U.S.C. § 121 set forth in the Office Action dated December 19, 2001, claims 1-19 were canceled without prejudice.

Independent claim 20 was previously amended in the Supplemental Amendment filed on August 1, 2002 consistent with the Examiner's suggestion during the interview of July 11, 2002 to change the term "comprised" to "consisting essentially" to overcome the 35 U.S.C. § 103(a) art rejection over US Patent No. 5,635,204 to Gevirtz et al (the '204 patent). Applicant hereby acknowledges the previous *withdrawal* of this rejection by the Examiner in the Office Action dated August 20, 2002. Claim 20 is being currently amended herein to correct an inadvertent typographical error and thereby omit the misspelled term "chlondine" from the claim. This amendment is believed to overcome the Examiner's rejection under 35 U.S.C. § 112, second paragraph. Independent claim 20 was also previously amended on February 20, 2003 to include the limitations of dependent claim 21 (namely to limit claim 20 a specific group of guanidine derivatives) and, accordingly, dependent claim 21 was canceled at that time.

Dependent claims 22-35 were previously presented. For the reasons set forth below, Applicant believes that claims 20 and 21-35 are in condition for allowance.

Independent claim 36 was previously amended on February 20, 2003 to include the limitations of dependent claim 37 (namely to limit claim 36 to a specific group of guanidine derivatives) and, accordingly, dependent claim 37 was canceled at that time. Independent claim 36 is also being currently amended herein to correct an inadvertent typographical error and thereby omit the misspelled term "chlondine" from the claim. This amendment is believed to overcome the Examiner's rejection under 35 U.S.C. § 112, second paragraph.

Independent claim 49 has been currently amended as set forth above pursuant to the Examiner's rejection under 35 U.S.C. § 112, first paragraph and now specifically includes the limitations of dependent claim 50, namely to identify a specific group of guanidine derivatives. Support for the amendment can be found throughout the specification, *e.g.*, at page 14, lines 22-25. Thus, no new matter is being added by the amendment. Please cancel claim 50 with out prejudice.

Thus, as set forth in the "Amendments to the Claims" above, claims 20, 22-36, 38-49 and 51-64 are currently pending in the application. The above amendments and the following remarks are believed to place the application in condition for allowance.

Objection to the Specification

As set forth on page 2 of the instant Office Action, the Examiner's objection to the specification is maintained with respect to Tables 1-3. In particular, the Examiner states that Tables 1-3 contain graphs that should be deleted from the specification and resubmitted as drawings. A section titled "Brief Description of the Drawings" should be added to the specification. MPEP 608.01 cites 37 CFR 1.58 "Chemical and mathematical formulae and tables" which recites that drawings may not be included in the specification. The Examiner notes Applicant's intent to amend the specification and submit formal drawings to replace Tables 1-3 upon receipt of a notice of allowability of the claimed invention.

In addition, the Examiner has objected to the disclosure and claims because of the following: compounds "clonidine" and "atipamezole" appear to be misspelled. Applicant will correct the spelling errors of the specification as required by the Examiner at the time of the correction of the specification to include formal drawings of Tables 1-3 and add the "Brief Description of the Drawings" is made (upon receipt of the notice of allowability). Applicant appreciates the Examiner's understanding and cooperation in this matter.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 49-64 are rejected because the specification, while being enabling for a guanidine derivative that posses the requisite .alpha. adrenergic receptor agonist activity, allegedly does not reasonably provide enablement for any and all guanidine derivatives. It is alleged that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. On pages 11 and 12 it is emphasized that the guanidine derivative employed in the method must possess .alpha. adrenergic receptor agonist activity.

Claim 49 has been amended above to include the limitations of dependent claim 50. In addition the misspelled term "chlonidine" has been omitted. The compounds now contained in amended claim 49 are specifically taught as examples of suitable quanidine derivatives in the specification. Thus, the amendment of Claim 49 is believed to overcome the Examiners rejection under 35 U.S.C. § 112, first paragraph. Therefore, claims 49 and 51-64 are believed to be in condition for allowance and withdrawal of the rejection § 112, first paragraph rejection is respectfully requested.

Rejection under 35 U.S.C.§ 112, second paragraph

Claims 20,22-36, 38-48, 50 are rejected as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As set forth above, claims 20 and 36 have been amended consistent with the Examiner's suggestion to correct the inadvertent typographical error and omit the term "chlonidine." In view of the above-amendments withdrawal of the rejection under 35 U.S.C. § 112, second paragraph is believed to be warranted.

Rejection under U.S.C. § 103(a)

As stated in the Office Action dated May 23, 2003, claims 20, 22-36, and 38-48 were rejected under 35 U.S.C.§ 103(a) as allegedly being unpatentable over US Patent 5,635,204 alone or in view of Veterinary Pharmacology and Therapeutics (Adams). However, during the telephone interview with the Examiner of December 4, 2003, the Examiner noted that the § 103(a) rejection of claims 20 and 22-35 in view of the '204 patent (originally set forth in the Office Action dated December 19, 2001) was previously withdrawn (*see*, page 3 of the Office Action dated August 20, 2002).

This rejection was specifically withdrawn by the Examiner in response to the interview of July 11, 2002, and the agreement reached therein to amend claim 20 to limit the claim to compositions consisting essentially of a guanidine derivative. As recognized by the Examiner, none of the cited references including the newly cited Veterinary Pharmacology and Therapeutics (Adams) teach or suggest the use of a single guanidine derivative for inducing a rapid onset sedation and analgesia in an animal.

With respect to claims 20 and 22-35, there is absolutely no teaching or suggestion anywhere in the '204 patent or in Adams of a method of rapid induction of long lasting sedation and analgesia via administration of a single guanidine derivative as set forth in independent claim 20. The use of a single guanidine derivative selected from the group set forth in amended claim 20 certainly cannot be obvious based upon the teachings of the '204 patent and Adams.

U.S. Patent No. 5,635,204 is directed to the use of a *required combination* of drugs to induce *general anesthesia* or a surgical stage of anesthesia in a recumbent individual. The specification of the '204 patent at column 2, lines 9-23 specifically recites the required combination of drugs for induction of *general anesthesia*, namely fentanyl or a fentanyl analog (line 12); an α_2-adrenergic agonist such as clonidine (lines 13-16); and an amnesia inducing drug such as ketammine (lines 17-19). General or surgical anesthesia

places an animal in recumbancy and increases the risk to the patient and, as set forth in the '204 patent, *requires* administration of additional drugs, namely narcotics and dissociative anesthetic agents such as fentanyl and ketamine respectively, which increase the risk of adverse reactions in the patient. The methods of claims 20 and 22-35 do not require administration of any agent other than a guanidine derivative for induction of the desired sedation and analgesia. The induction of the desired sedation and analgesia cannot be obvious in view of the teachings of the '204 patent.

Likewise, Adams, teaches that the alpha adrenergic agonists are used as preanesthetic agents (See, Table 9.9 (4)) and are advocated as such where "the concurrent use of two or three drugs is usually required to accomplish the required preanesthetic conditions in the patient" and Adams notes that "unfortunately, preanesthetic medication is not without its complications"(See, page 160, column 2). Thus, Adams teaches the use of alpha adrenergic agonists such as Xylanine for use as a preanesthetic agent for which a subsequent drug is administered to achieve the desired anesthetic effect as is required in the '204 patent. Neither reference teaches or suggests the of a single guanidine derivative as set forth in independent claim 20. Therefore, withdrawal of the rejection of claims 20, and 22-35 under § 103(a) is believed to continue to be warranted and is respectfully requested.

The above remarks are equally applicable to claims 36 and 38-48 which were also rejected in the instant office action under § 103(a) over the '204 patent alone or in view of Adams. Claims 36 and 38-48 are directed to a method for inducing rapid onset and long lasting sedation and analgesia <u>in a standing equine animal</u> which further distinguishes over the cited art. There is no teaching or suggestion of the use of a quanidine derivative in a single administration to a standing equine animal to achieve the desired effect.

Likewise, claims 49 and 51-64 are directed to a method for providing *chemical restraint* of an animal, comprising administering to the animal a pharmaceutically effective amount of a composition comprised of a selected guanidine derivative. There is

no suggestion in the '204 patent or Adams of the single administration of a quanidine derivative for acheiving the desired effect. Both references teach the use of required combinations of drugs and multiple timed administrations to achieve a desired level of anesthesia. As demonstrated in Applicant's video at the July 11, 2002 interview, a single administration of a guanidine derivative produced profound sedation and analgesia and an effective means of a rapidly reversible *chemical restraint* in animals, especially large animals, *e.g.*, horses. There is absolutely no teaching or suggestion anywhere in the '204 patent or Adams of a method for providing for chemical restraint of animals via the single administration of a selected guanidine derivative as required by the instant claims.

Thus, claims 49 and 51-64 are believed to be free of art and are believed to be in condition for allowance. None of the art of record teaches or suggests a method for providing *chemical restraint* of an animal, comprising the single administration to an animal of a pharmaceutically effective amount of a composition comprised of a selected guanidine derivative.

Accordingly, in view of the amendment of claims 20, 36 and 49 and the remarks set forth above, withdrawal of the rejection of under 35 U.S.C. § 103(a) is believed to be warranted and is earnestly solicited.

Related Matters

In the Amendment submitted on November 24, 2003, the Assistant Commissioner was authorized to debit Deposit Account No. 19-4430 the amount of $ 475.00 for the fee for a three month extension of time. No additional fee is believed to be due at this time, however, the Commissioner is hereby authorized to debit deposit account number 19-4430 for any additional fees deemed to be due or issue a credit for any overpayment thereof. The Examiner is encouraged to contact the undersigned attorney directly if such contact will enhance the efficient prosecution of the application to issue.

Respectfully submitted,

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Certificate of Facsimile Transmission

I hereby certify that a courtesy copy of this correspondence is being transmitted by facsimile to Examiner Rebecca Cook at: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, to telephone number **(703) 872-9306** and to telephone number **(703) 308-4556** on:

January 20, 2004
Date

J. W. Seanor DVM
By